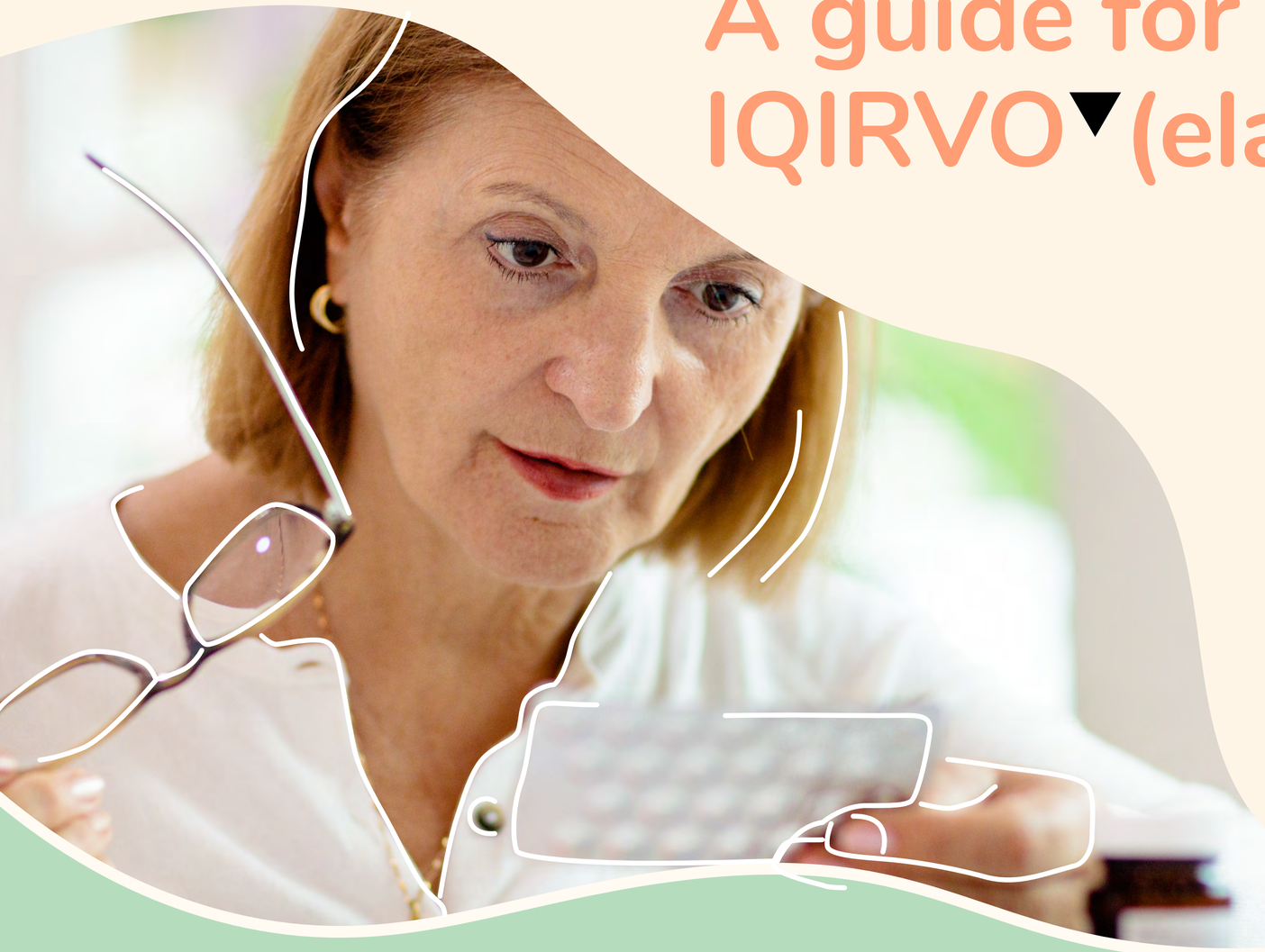
This guide is intended for patients with PBC who have been prescribed IQIRVO▼ (elafibranor).

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A guide for patients prescribed IQIRVO▼ (elafibranor)

For people living with primary biliary cholangitis (PBC)



This resource contains important information about IQIRVO (elafibranor), including what it is, how it works, and what to expect with this treatment.

For full information, please refer to the patient information leaflet that came with the medication.

IPSEN IN PBC

IQIRVO (elafibranor) Patient Support

What is PBC?

PBC is known as an **autoimmune disease,** meaning that the immune system (the body's defence mechanism against illness) mistakes healthy cells, tissues, or organs for something dangerous for the body.[1,2] As a result, the immune system falsely attacks and destroys a healthy part of the body, which can impair its ability to function correctly. In PBC, this happens in the liver.[2]

PBC is a fairly rare liver condition that can progress over time and lead to scarring of the liver (**fibrosis**), more advanced liver scarring (**cirrhosis**), and liver failure if left untreated.[1] Fortunately, there are treatments for PBC that can help how your liver works and help with your symptoms (and will be mentioned in more detail in further sections).[1]

What is elafibranor?

Elafibranor is a treatment that has been prescribed to you. Your healthcare professional might also refer to elafibranor as IQIRVO®. In this booklet, we will refer to the medicine as elafibranor.

Elafibranor might be prescribed to someone if...

they were taking ursodeoxycholic acid (UDCA), but it was not fully effective. In this case, elafibranor can be given together with UDCA.[3]

they were taking UDCA but were experiencing intolerable side effects, in which case elafibranor can be taken instead of UDCA.[3]

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This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard/ for how to report side effects.

Side effects should also be reported to Ipsen via email at pharmacovigilance.uk-ie@ipsen.com or phone on 01753 627777.

Patient’s Guide to Elafibranor: Glossary terms

The following terms are used throughout this booklet. We have provided an explanation here for what they mean so that you can refer back to this if needed when reading the booklet.

Alkaline phosphatase (ALP)[4,5]
An enzyme that is released into the blood when bile ducts are damaged. Levels of ALP in the blood are elevated in people with PBC.

Autoimmune disease[6]
Health conditions that occur when the immune system mistakes healthy cells, tissues, or organs for something harmful.

Bile[7,8]
A fluid produced by the liver that is involved in digestion and waste elimination.

Bilirubin[8]
Yellow pigment found in bile. Testing for bilirubin in the blood is used to evaluate liver health. Bilirubin levels might be higher than normal if the liver is having trouble processing it, or if the bile ducts are blocked.

Cirrhosis (liver)[5,9]
Severe scarring that impairs organ function and can develop into health complications. Cirrhosis occurs if **fibrosis** progresses and worsens. There are different levels of liver cirrhosis. In people with compensated cirrhosis, the liver can function almost as normal, whereas decompensated cirrhosis indicates that the liver is failing.

Fibrosis (liver)[9]
Scarring of the liver that can lead to liver cirrhosis.

Placebo[10]
Something that seems to be a medicine, but is actually a pill, tablet or other administration that contains nothing that will impact your health. This is helpful for comparing to an actual medicine, as it removes effects that may have been the result of a perceived impact (placebo effect) of taking that medicine.

Primary biliary cholangitis (PBC)[5]
A long-term, autoimmune liver condition affecting bile ducts. The destruction of bile ducts in PBC causes cholestasis, and bile builds up in the liver. This can lead to liver damage and cirrhosis if left untreated.

Ursodeoxycholic acid (UDCA)[5]
UDCA is a type of bile salt that can help clear bile from your liver and reduce liver damage.

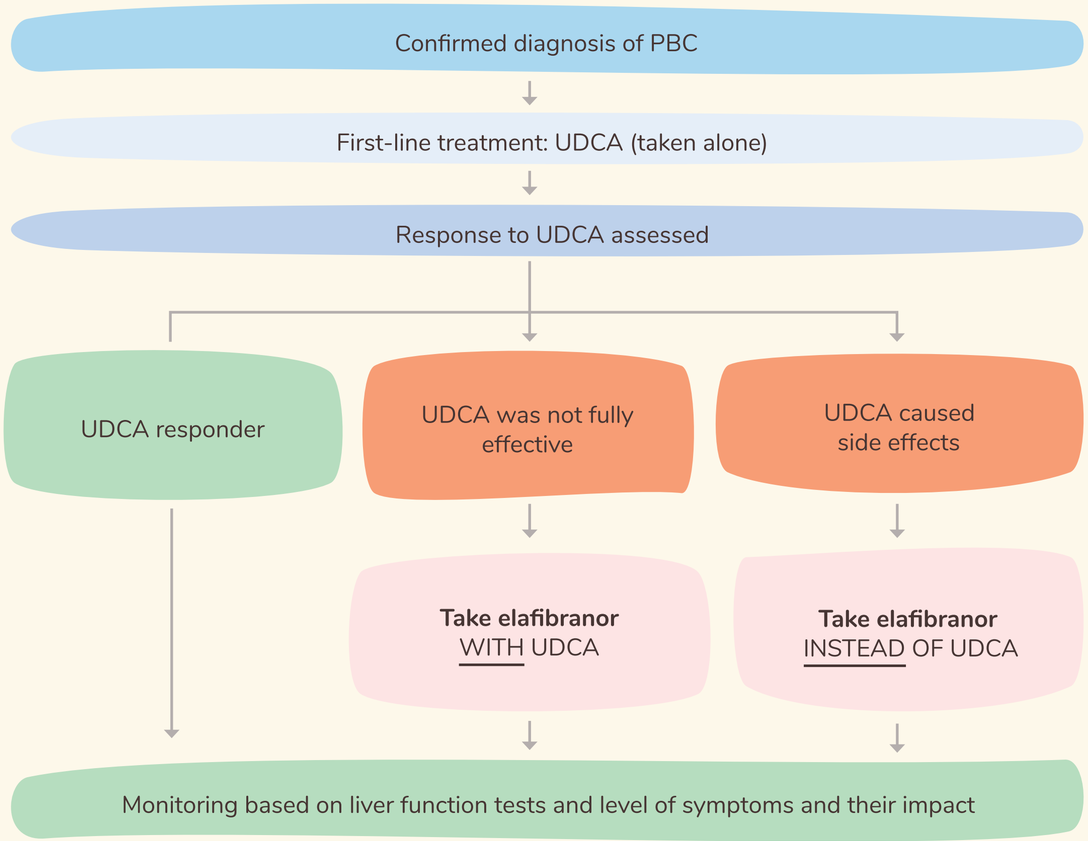


PBC fact

PBC was previously referred to as **primary biliary cirrhosis**, leading to the misconception that it could be caused by drinking alcohol. This is **not true**, and PBC is believed to be influenced by **multiple factors**. The new name, primary biliary **cholangitis**, helps to avoid the confusion.[11]

Where does elafibranor sit in the PBC care pathway?

Elafibranor is known as a “second-line” treatment, meaning that it can only be given to people who have previously received “first-line” treatment with UDCA.The flow-chart below provides a simplified overview of how your healthcare professional decides on the medication that is most appropriate for you.[3,12]*



*Adapted from the European Association for the Study of the Liver (EASL) Clinical Practice Guidelines[12]
†Patients may have recieved other second-line treatments before elafibranor[3,12]

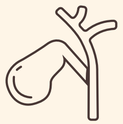


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How does elafibranor work?

Elafibranor works by activating small proteins in the body called **peroxisome proliferator-activated receptors (PPARs)**.[3] Studies have shown that activating PPARs may help to control PBC:

Effects of activating PPARs on the liver



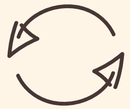
Decreases the amount of bile being made[13,14]



Decreases liver inflammation [13-15]



Decreases liver fibrosis[13-15]



Increases removal of bile[12-14]



Increases the breakdown of fats by the liver[13-15]



How does this help people with PBC?

Elafibranor was studied in a clinical trial called “**ELATIVE**” during which 161 people received elafibranor or placebo for at least a year.[16]

After one year of treatment in the ELATIVE trial, people who took elafibranor had lower levels of **alkaline phosphatase (ALP)** and **bilirubin** than those taking placebo. ALP and bilirubin are important measures for liver disease. Some people experienced a reduced impact of itching on their daily lives after taking elafibranor.[3,16]

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Important information about elafibranor

Consider the following before you start taking elafibranor and talk to your healthcare professional if you have any questions or concerns.

Pregnancy and contraception



The use of elafibranor is not recommended during pregnancy or in women of child-bearing age who are not using effective contraception.[3]

If elafibranor is prescribed, effective contraception must be used throughout elafibranor treatment and for 3 weeks after stopping.[3]

Your doctor may ask you to take a pregnancy test before starting treatment with elafibranor to ensure you are not pregnant prior starting treatment.[3]

Do not breast-feed whilst taking this medicine as it is unknown if elafibranor will pass to your child in your milk.[3]

Please speak with your healthcare professional or another member of your healthcare team if you have any concerns, or if you would like more information about the types of **effective contraception**.

Because Iqirvo may reduce the effictiveness of hormonal birth control (such as pills, injections, patches, implants and certain intrauterine devices (IUDs) that release hormones), you should use a different method of birth control, such as a non-hormonal IUD (intrauterine device) or add a barrier method (e.g. condom) so you do not become pregnant while you are taking this medicine.

If you fall pregnant, suspect you are pregnant, or are planning to become pregnant while taking elafibranor, please inform your healthcare professional.[3]

Allergies

If you have been told you are allergic or hypersensitive to common ingredients used in medications, please tell your healthcare professional.[3] They will check your allergies against a list of elafibranor ingredients. If you experience a hypersensitivity reaction, such as a rash, please contact your healthcare professional, call 111, or visit your nearest emergency care centre.[3]

Potential side effects



Like all medicines, this medicine can cause side effects, although not everybody gets them. In a clinical trial using elafibranor, the most common side effects were abdominal pain, diarrhoea, nausea, and vomiting. They were all considered non-serious and mild to moderate in severity.[3]

Liver function and muscle pain

Talk to your doctor or pharmacist before taking elafibranor if you have severely reduced liver function, or if you have previous history of unexplained muscle pain.[3]

Talk to your doctor immediately if you experience unexplained muscle pain, soreness or weakness whilst taking this medicine.[3]

Your doctor may carry out blood tests before prescribing elafibranor to you, and during the course of your treatment. Your doctor may also tell you to stop elafibranor temporarily or permanently if there are changes to either your liver function tests or the level of an enzyme in your blood called creatine phosphokinase.[3]

Uncommon

(between 1 in 100 and 1 in 1000 people)

- Itchy rash
- Increase in blood creatinine levels

Common

(between 1 in 10 and 1 in 100 people)

- Headache
- Constipation
- Gallstones
- Muscle soreness
- Increase in blood creatine phosphokinase (CPK) levels

Very common

(more than 1 in 10 people)

- Abdominal pain
- Diarrhoea
- Nausea (feeling sick)
- Vomiting (being sick)

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How to take elafibranor

Elafibranor should be taken orally **once a day**, with or without food.[3] The recommended dose is **80 mg (a single tablet)**. The tablet should not be crushed, chewed or split prior to administration.[3]

If you miss a daily dose, do not take a double dose. Instead, skip the missed dose and take the next one when it is due.[3]

If you have taken more of this medicine than you have been instructed to, talk to a doctor or go to the hospital taking the tablets and this leaflet with you straight away.

Do not stop taking this medicine unless you have discussed this with your doctor.

How to store elafibranor

Store at room temperature (15°C to 30°C) in the original package to protect from moisture and light.[3] After first opening, the product may be stored for a maximum of 30 days.[3]

For more information about elafibranor, speak to your healthcare professional.

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